REMARKS

This responds to the Office Action dated December 8, 2004. Claims 73, 76, 77, 79, 131, 134, 138, 143 and 147 have been amended. Applicant requests reconsideration of the amended claims based on the comments made herein and also requests that the application be allowed and passed to issue.

Applicant appreciates the Examiner's time and consideration in entering the 37 C.F.R. 1.132 affidavits. The Applicant also appreciates the efforts of Examiner Morgan and Primary Examiner Kalinowski in participating in the telephonic interview Applicant's attorney, Cheryl Bab, on February 9, 2005. Three prior art references were discussed during the interview: Machlis, "Web links cancer patients to drug trials," Oct. 14, 1998 ("Machlis"), U.S. Patent No. 5,991,731 to Colon et al and U.S. Patent No. 6,171,112 to Clark et al. An agreement was reached that Machlis does not teach the element of electronic consent based on the argument which is set forth below. However, the Examiners raised an issue as to whether the "individual" recited in each of the independent claims is the "potential candidate." Applicant respectfully asserts that the claims as presented make clear that the individual is the potential candidate because the claims generally recite that the individual provides his personally identifying information or medical information. Such personally identifying information or medical information is then added to a database of potential candidates. The only individual who would provide his personally identifying or medical information is the person who is volunteering as a potential candidate. Therefore, the claims as presently pending clearly recite that the individual is the potential candidate. Moreover, presently pending claim 143 explicitly recites that "an individual who has volunteered as a potential candidate for a plurality of clinical trials." However, to address the Examiners' concerns, applicant has added new claims 150-156 which add the recitation that the individual is the potential candidate.

The Examiner rejected claims 73-74, 96, 102-104, 131-136, 137-139, 141-143, 146 and 149 under 35 U.S.C. 103(a) as being unpatentable over Colon in view of Machlis. See the Office Action, paragraph 4, page 2. Claims 73, 131, 132, 134, 138, 141 and 143 are independent. The arguments presented below were addressed during the telephonic interview and Applicant's attorney concluded from the Examiners' remarks that the rejections based on Machlis have been overcome.

The Examiner asserts that Colon "fails to teach electronic consent to an agreement volunteering for consideration as a potential candidate for [] clinical trials." (Office Action, page 3.) The Examiner then presents the teachings of Machlis. However, no where in Machlis nor in the Examiner's asserted teachings is taught an individual's on-line electronic consent to an agreement volunteering for consideration as a potential candidate -- an element of each of the independent claims. The Examiner asserts that "Machlis teaches that the patient can decide if they want to try a new therapy (see paragraph 11)" (Office Action, paragraph 4, page 3). However, this is not a teaching of a consent by the patient to volunteer for consideration as a patient in clinical trials. There is no teaching in Machlis that consent is provided by the patient. Indeed, there is no teaching in Machlis that the patient is provided with an opportunity to give consent. It is the doctor who interacts entirely with the software system. To the extent that doctor does not facilitate the relationship between the patient and the system administrator, the patient does not have access to it. Indeed, when a match occurs, it is not the patient who is contacted but the doctor. The invention as claimed represents a paradigm shift of control over access to clinical trials from doctors directly to patients.

Regarding the Examiner's assertion that a patient's decision to try a new therapy is consent, in Machlis, doctors enter the information because the system "is only open to doctors" (paragraph 9) and doctors communicate to the patient that a trial is available -- "[d]octors are emailed if any of their patients might match the trial" (paragraph 10). It is only then that the Machlis article provides that "[p]atients can decide if they want to try a new therapy" (paragraph 11). The patient's input therefore is at the point of deciding whether to enroll in a clinical trial which is brought to their attention by their doctor.

The invention as claimed places the ability to be considered for clinical trials directly in the patients hands rather than in the doctors hands. As a result, Machlis does not teach at least one element of each of the independent claims (and the claims which depend from them). Applicant therefore respectfully requests that the 103 rejections be withdrawn because at least one element of each of the rejected claims is not taught by any of the cited prior art references. As a result, claims 73, 131, 132, 134, 138, 141 and 143 and the claims which depend from them are allowable and should be passed to issue.

In addition, the Examiner asserts that independent claim 147 is rejected under 35 U.S.C. 103 as being unpatentable over Machlis in view of Clark. Claim 147 also recites the consent element

described above. Machlis does not teach such element, nor does Clark. Therefore, applicant respectfully asserts that the 103 rejection be withdrawn and claim 147 be allowed and passed to issue.

The Examiner further asserts rejections under 35 U.S.C. 103 of dependent claims (see the Office Action, paragraphs 5 (page 14), 6 (page 21), 7 (page 22), 8 (page 23) and 10 (page 25)). The Examiner identifies the following prior art references in these rejections: Colon, Machlis, Clark, U.S. Patent No. 6,272,470 to Teshima and Official Notice of prior art teachings. Each of the dependent claims which are rejected derives from an independent claim. None of the additional prior art references nor the subject of the Official Notices teaches the consent element recited in each of the independent claims, as described above. Since the independent claims are allowable, the dependent claims are likewise allowable. Applicant therefore respectfully requests that the 103 rejections of the dependent claims be withdrawn and the claims be allowed and passed to issue.

The Colon and Clark references also were discussed during the telephonic interview. In particular, the Examiners asserted that the combination of Colon and Clark can be applied to teach the independent claims, for example, claim 73. In order to apply the Colon and Clark references to the pending independent claims, for example, claim 73, each element of the claim must be taught by one of the prior art references. This is not the case here. The Examiner asserted in the Office Action that Machlis teaches the electronic consent to volunteer as a potential candidate. During the interview, the Examiner agreed to withdraw that argument. Therefore, Machlis does not teach such element. In addition, neither Colon nor Clark teaches electronic consent for volunteering as a potential candidate. Colon does not teach such element and the Examiner does not argue that it does. Clark involves a patient giving electronic consent to a doctor for a medical procedure. The Clark teaching amounts to merely transforming a transaction done in hard copy, that is, providing a doctor with consent, into electronic form. The transaction happens to occur in the medical field. There is no teaching of the patient providing to a third party his electronic consent to be considered for clinical trials. In fact, there is not cited prior art reference that provides that teaching. The pending claims do not involve an ordinary transaction between doctor and patient that is transformed into an electronic transaction. It is a paradigm shift from a transaction involving a medical procedure between a patient and a doctor with the doctor as the conduit to a transaction involving a patient and a third party (i.e., an administrator of clinical trials) with the patient communicating with the

administrator(s) to the exclusion of the doctor. Therefore, Clark cannot be combined with Colon to provide the teaching of electronic consent to volunteer for clinical trials. Since there is not cited prior art reference which provides the teaching of electronic consent to volunteer for clinical trials, applicants respectfully request that the pending claims be allowed and passed to issue.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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